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8 UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WASHINGTON

9 UNITED STATES OF AMERICA,

No. CV-11-3101-EFS

10 Plaintiff,

**CONSENT DECREE**

11 v.

12 Seven 25 pound cases, more or less, of  
13 an article of food, labeled in part:

14 (case)

15 “ \*\*\* WHOLE PAPRIKA \*\*\* NET  
WEIGHT: 25 Lb. \*\*\* PRODUCT OF  
16 PERU \*\*\* DISTRIBUTOR: MISKI  
INC. \*\*\* MIAMI, FL 33129 \*\*\* ”

17 and

18 other articles of food in various sizes  
19 and types of containers, that are  
located on the premises of Dominguez  
20 Foods of Washington, Inc., 104 5th  
Street, Zillah, Washington, to which  
21 are affixed labels bearing, among  
other things, the name and address of  
22 the manufacturer, packer, or  
distributor located outside the state of  
23 Washington, or otherwise determined  
to have originated from outside the  
24 state of Washington, that are currently  
held under FDA detention notice  
25 DN00002, dated 9/2/11,

26 Defendants,

27 And  
28

CONSENT DECREE

1 Dominguez Foods of Washington,  
2 Inc.,

3 Claimant.

4  
5 **CONSENT DECREE OF CONDEMNATION AND PERMANENT**  
6 **INJUNCTION**

7 On September 29, 2011, the United States of America ("Plaintiff"), by and  
8 through its attorneys, filed a Verified Complaint for Forfeiture *In Rem*  
9 ("Complaint") against the above-described articles (the "Articles"). The  
10 Complaint alleges that the Articles proceeded against are articles of food that are  
11 adulterated, within the meaning of the Federal Food, Drug, and Cosmetic Act ("the  
12 Act"), 21 U.S.C. § 342(a)(4), while held for sale after shipment in interstate  
13 commerce, in that they have been held under insanitary conditions whereby they  
14 may have become contaminated with filth. The Complaint further alleges that the  
15 Articles are being held illegally within the jurisdiction of this Court and, therefore,  
16 are liable for seizure and condemnation under the Act, 21 U.S.C. § 334.

17 Pursuant to a Warrant of Arrest *In Rem* issued by this Court, the United  
18 States Marshal for this District seized the Articles on September 30, 2011. On  
19 November 1, 2011, Dominguez Foods of Washington, Inc. ("Claimant"), through  
20 its attorneys, intervened and filed a claim to the Articles. No other party has filed a  
21 claim to the Articles.

22 WHEREAS Claimant, having appeared and voluntarily consented to the  
23 entry of this Decree without admitting or denying the allegations of the Complaint,  
24 before any testimony has been taken, and waiving the filing and service of an  
25 amended complaint seeking injunctive relief, and the United States having  
26 consented to this Decree:



1 IT IS HEREBY ORDERED, ADJUDGED, AND DECREED THAT:

2 1. This Court has subject matter jurisdiction over this action pursuant to  
3 28 U.S.C. § 1345 and 21 U.S.C. §§ 332 and 334, and personal jurisdiction over all  
4 parties to this action. Venue is proper in this district under 28 U.S.C. §§ 1391  
5 (b)–(c) and 1395.

6 2. The Articles are articles of food that are adulterated, within the  
7 meaning of 21 U.S.C. § 342(a)(4), while held for sale after shipment in interstate  
8 commerce, and are, therefore, condemned pursuant to 21 U.S.C. § 334(a) and  
9 forfeited to the United States.

10 3. Claimant affirms that it is the sole owner of the Articles, and that no  
11 other person has an interest in the Articles. Claimant shall indemnify and hold the  
12 United States harmless should any party or parties hereafter file or seek to file a  
13 claim or to intervene in this action and obtain any part of the Articles.

14 4. Claimant shall pay to the United States all court costs and fees,  
15 storage, and other proper expenses, and such further costs for which Claimant is  
16 liable pursuant to 21 U.S.C. § 334(e). Claimant shall pay these costs within ten  
17 (10) calendar days after receiving notice of such costs from the United States Food  
18 and Drug Administration (“FDA”), the United States Marshals Service, and/or the  
19 United States Attorney’s Office for this District.

20 5. Within twenty (20) calendar days after the entry of this Decree,  
21 Claimant shall execute and file with the clerk of this Court a good and sufficient  
22 penal bond (“Bond”) with surety in the amount of one hundred thousand dollars  
23 (\$100,000.00). The Bond shall be in a form acceptable to the clerk of this Court  
24 and payable to the United States of America, and conditioned on Claimant abiding  
25 by and performing all of the terms and conditions of this Decree and of such  
26 further orders and decrees as may be entered in this proceeding.

27 6. Within twenty (20) calendar days after filing the Bond pursuant to  
28 paragraph 5, Claimant, at its own expense, shall retain an individual or individuals

1 (the "Expert") with no personal or financial ties (other than the retention  
 2 agreement) to Claimant, its officers, or directors, or their families, and who, by  
 3 reason of education, training, and experience, is qualified to develop and  
 4 implement a plan to bring the Articles into compliance with the Act. Upon  
 5 retaining the Expert, Claimant shall inform FDA in writing of the name and  
 6 qualifications of said Expert. Claimant shall not commence, or permit any other  
 7 person to commence, attempting to bring the Articles into compliance with the Act  
 8 unless and until:

- 9 a. the Expert develops and Claimant submits to FDA a written  
 10 proposal to bring the condemned Articles into compliance with  
 11 the Act ("Reconditioning Proposal");
- 12 b. Claimant receives written approval of the Reconditioning  
 13 Proposal from FDA; and
- 14 c. Claimant receives written authorization from FDA to  
 15 commence attempting to bring the Articles into compliance  
 16 with the Act.

17 7. Following Claimant's payment of costs and posting of the Bond, as  
 18 required by paragraphs 4 and 5 of this Decree, and following Claimant's receipt of  
 19 written authorization to commence attempting to bring the Articles into  
 20 compliance with the Act as described in paragraph 6.c, the United States Marshal,  
 21 upon receiving notice from the United States Attorney or FDA, shall release the  
 22 Articles from his custody to the custody of Claimant for the sole purpose of  
 23 attempting to bring such Articles into compliance pursuant to the Reconditioning  
 24 Proposal approved pursuant to paragraph 6.b, and under FDA supervision.

25 8. Within sixty (60) calendar days after receiving written authorization  
 26 to commence attempting to bring the Articles into compliance with the Act,  
 27 Claimant shall complete its attempt in accordance with the FDA-approved  
 28 Reconditioning Proposal, and under FDA supervision. Within ten (10) calendar



1 days after the expiration of this sixty (60) day period, Claimant shall destroy, at its  
2 expense and under FDA supervision, all Articles in its custody or control that have  
3 not been brought into compliance with the Act, and shall file a notice with the  
4 Court certifying that such Articles have been destroyed.

5         9. If, within ninety (90) days after entry of this decree, Claimant does not  
6 avail itself of the opportunity to repossess the Articles, or fails to submit a  
7 Reconditioning Proposal that is acceptable to FDA, or if any portion of the  
8 condemned Articles remain in the custody of the United States Marshal after  
9 expiration of the sixty (60) day time period described in paragraph 8, the United  
10 States Marshal shall destroy the articles and make due return to this Court  
11 regarding their disposition. Claimant shall bear the costs of storage and destruction  
12 that are incurred by the United States pursuant to this paragraph, and shall pay such  
13 costs within ten (10) calendar days after receiving an invoice from FDA, the  
14 United States Marshals Service, or the United States Attorney's Office.

15         10. Claimant shall not directly or indirectly cause or permit the shipment,  
16 sale, or other disposal of the Articles unless and until FDA has had free access to  
17 the Articles, in order to take any samples or perform any tests or examinations that  
18 FDA deems necessary, and FDA has released, in writing, the Articles for shipment,  
19 sale, or other disposition.

20         11. Claimant shall at all times, until the Articles have been released  
21 pursuant to paragraph 10, retain the Articles intact for examination or inspection by  
22 FDA in a place made known to and approved by FDA, and shall maintain the  
23 records or other proof necessary to establish the identity of the articles to the  
24 satisfaction of FDA.

25         12. Claimant shall not sell, ship, or dispose of, or permit or cause another  
26 person to sell, ship, or dispose of the Articles in a manner contrary to the Act, or  
27 contrary to other laws of the United States, or of any State or Territory (as defined  
28 in the Act) in which they are disposed of or sold.

1           13. If Claimant breaches any condition of this Decree, or any subsequent  
 2 decree or order in this proceeding, it shall, at its own expense, immediately return  
 3 Articles in Claimant's custody or control that have been released pursuant to  
 4 paragraphs 7 or 10 to the United States Marshal, or otherwise dispose of them at its  
 5 own expense pursuant to further order of this Court. In the event that return of any  
 6 of the Articles becomes necessary pursuant to this paragraph, Claimant shall be  
 7 responsible for all costs of storage and disposition that are incurred by the United  
 8 States.

9           14. If Claimant fails to abide by and perform all the terms and conditions  
 10 of this Decree, or of the Bond, or any such further order or decree as may be  
 11 entered in this proceeding relating to the Articles, then, on motion of the United  
 12 States in this proceeding, the Bond shall be forfeited in its entirety to the United  
 13 States and judgment entered thereon in favor of Plaintiff. Any Articles remaining  
 14 in the custody or control of either Claimant or the United States Marshal shall be  
 15 destroyed by the United States Marshals Service pursuant to the terms in paragraph  
 16 9 of this Decree.

17           15. The United States Attorney, upon being advised by FDA that all of  
 18 the Articles have been brought into compliance pursuant to the FDA-approved  
 19 Reconditioning Proposal or destroyed in compliance with this Decree, and that  
 20 Claimant has paid all costs as of that date, will <sup>file a motion with the Court seeking</sup> ~~transmit such information to the~~  
 21 ~~return of the bond to the Claimant.~~  
 22 ~~clerk of this Court, whereupon the Bond given in this proceeding shall be returned~~  
 23 ~~to the Claimant.~~

24           16. Within fourteen (14) calendar days after the entry of this Decree,  
 25 Claimant shall certify in writing to FDA that it has taken corrective actions  
 26 necessary to render its food storage and processing facility located at 104 5th Street  
 27 in Zillah, Washington (the "Facility") fit for the storage and handling of food.  
 28 Claimant shall further submit in writing to FDA a detailed list of the corrective



1 actions taken, including documentation sufficient to demonstrate that such actions  
2 were taken.

3 17. Within thirty (30) calendar days after entry of this Decree, Claimant  
4 shall certify in writing to FDA that it has prepared and implemented a written  
5 sanitation control program (the "Sanitation Control Program"), which shall include  
6 adequate methods and controls to ensure that the condition and operation of the  
7 Facility do not render food held therein adulterated within the meaning of 21  
8 U.S.C. § 342(a), and comply with the requirements of 21 C.F.R. Part 110.  
9 Claimant shall certify in writing that it has assigned responsibility for the  
10 Sanitation Control Program to an individual or individuals who, by reason of  
11 education, training, and experience in sanitation work, is or are competent to  
12 continuously implement the Sanitation Control Program (the "Responsible  
13 Individual"). Claimant shall submit in writing to FDA a copy of the Sanitation  
14 Control Program and the qualifications of the Responsible Individual.

15 18. Within thirty (30) calendar days after entry of this Decree, Claimant  
16 shall retain at its expense, an independent person or persons (the "Auditor") with  
17 no personal or financial ties (other than the retention agreement) to Claimant, its  
18 officers, or directors, or their families, who is qualified by education, training, and  
19 experience to assess Claimant's compliance with the Act and its implementing  
20 regulations, and shall notify FDA in writing of the Auditor's qualifications as soon  
21 as the Auditor is retained. Thereafter:

- 22 a. The Auditor shall conduct audit inspections of the Facility to  
23 evaluate whether Claimant is in compliance with the Act and its  
24 implementing regulations. The first such audit inspections shall  
25 be conducted not later than six months after the entry of this  
26 Decree and not less than once every twelve months thereafter  
27 for a period of four years, for a total of not less than five audits.  
28

- 1           b.    At the conclusion of each audit inspection, the Auditor shall  
2               prepare a written report identifying in detail any objectionable  
3               conditions at the Facility that could render articles of food held  
4               therein adulterated within the meaning of 21 U.S.C.  
5               § 342(a)(4). The reports shall be delivered to the Claimant and  
6               FDA no later than twenty (20) calendar days after the date each  
7               audit inspection is completed.
- 8           c.    If a report identifies objectionable conditions, Claimant shall,  
9               within ten (10) calendar days after receipt of the report, make  
10              all necessary corrections. If Claimant concludes that corrective  
11              action cannot be achieved within ten (10) calendar days,  
12              Claimant shall notify FDA in writing of the basis for its  
13              conclusion and a proposed schedule for completing the  
14              corrective actions that does not exceed thirty (30) calendar  
15              days.
- 16           d.    Claimant shall make the corrections in accordance with the  
17               proposed schedule, unless FDA notifies Claimant in writing  
18               that a shorter time frame is required.
- 19           e.    Within ten (10) calendar days of the required completion date  
20               for corrective actions, the Auditor shall review the corrective  
21               actions taken by Claimant and report in writing to FDA whether  
22               each objectionable condition has been corrected.

23           19. If at any time after entry of this Decree, Claimant is advised in writing  
24           by FDA that conditions in the Facility render articles of food held therein  
25           adulterated within the meaning of 21 U.S.C. § 342(a)(4), Claimant shall  
26           immediately, upon such notification, discontinue receiving articles of food in  
27           interstate commerce and discontinue introducing, delivering for introduction, and  
28           causing the introduction or delivery for introduction into interstate commerce



1 articles of food prepared, packaged, or held by Claimant at the Facility, unless and  
2 until:

- 3 a. FDA, as it deems necessary, inspects the Facility in order to  
4 determine whether the Facility and articles of food processed or  
5 held therein are in compliance with the Act, its implementing  
6 regulations, and this Decree. All costs of such inspection(s)  
7 shall be borne by Claimant;
- 8 b. Claimant provides FDA access to all records relating to the  
9 receipt, storage, and shipment of articles of food, and to the  
10 sanitation of the Facility, as FDA deems necessary, and upon  
11 FDA's request; and
- 12 c. FDA authorizes Claimant in writing to resume receiving and  
13 introducing articles of food in interstate commerce.

14 The provisions of this paragraph shall be apart from, and in addition to, all  
15 other remedies available to FDA.

16 20. Upon entry of this Decree, Claimant and each and all of its directors,  
17 officers, agents, employees, representatives, successors, assigns, attorneys, and any  
18 and all persons in active concert or participation with any of them (the "Associated  
19 Person(s)") who receive notice of this Decree, are permanently restrained and  
20 enjoined under the provisions of 21 U.S.C. § 332(a) from causing articles of food  
21 to become adulterated within the meaning of 21 U.S.C. § 342(a)(4).

22 21. Within ten (10) calendar days after entry of this Decree, Claimant  
23 shall post a copy of this Decree in a common area at the Facility and at any other  
24 location at which Claimant conducts business, and shall ensure that the Decree  
25 remains posted for as long as the Decree remains in effect.

26 22. Within ten (10) calendar days after entry of this Decree, Claimant  
27 shall provide a copy of the Decree by personal service or certified mail (return  
28 receipt requested) to each of the Associated Person(s). Within thirty (30) calendar

1 days after entry of this Decree, Claimant shall provide to FDA an affidavit stating  
2 the fact and manner of their compliance with this paragraph, identifying the names,  
3 addresses, and positions of all persons who have received a copy of this Decree.

4       23. In the event that Claimant becomes associated with any additional  
5 Associated Person(s) at any time after entry of this Decree, Claimant shall  
6 immediately provide a copy of this Decree, by personal service or certified mail  
7 (restricted delivery, return receipt requested), to such Associated Person(s). Each  
8 time Claimant becomes associated with an additional Associated Person(s),  
9 Claimant shall, within ten (10) calendar days, provide to FDA an affidavit stating  
10 the fact and manner of their compliance with this paragraph, identifying the names,  
11 addresses, and positions of all Associated Person(s) who received a copy of this  
12 Decree pursuant to this paragraph. Within ten (10) calendar days after receiving a  
13 request from FDA for any information or documentation that FDA deems  
14 necessary to evaluate Claimant's compliance with this paragraph, Claimant shall  
15 provide such information or documentation to FDA.

16       24. Claimant shall notify FDA in writing at least fifteen (15) calendar  
17 days before any change in ownership, name, or character of its business that occurs  
18 after entry of this Decree, including an incorporation, reorganization, creation of a  
19 subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other  
20 change in the structure or identity of Dominguez Foods of Washington, Inc., or the  
21 sale or assignment of any business assets, such as buildings, equipment, or  
22 inventory, that may affect obligations arising out of this Decree. Claimant shall  
23 provide a copy of this Decree to any prospective successor or assign at least thirty  
24 (30) calendar days prior to any sale or assignment. Claimant shall furnish FDA  
25 with an affidavit of compliance with this paragraph no later than ten (10) calendar  
26 days prior to such assignment or change in ownership.

27       25. FDA shall be permitted, without prior notice and as and when FDA  
28 deems necessary, to make inspections of the Facility, and, without prior notice,



1 take any other measures necessary to monitor and ensure continuing compliance  
2 with the terms of this Decree. During inspections of the Facility, FDA shall be  
3 permitted to take photographs and make video recordings; to take samples of  
4 articles of food and packaging material(s); to examine and copy all records relating  
5 to the receiving, manufacturing, preparing, packing, holding, and distributing of  
6 any and all articles of food, and to the maintenance and condition of the Facility.  
7 The inspection authority granted by this Decree is separate from, and in addition  
8 to, the authority to make inspections under the Act, 21 U.S.C. § 374.

9       26. Claimant shall reimburse the United States for the costs of supervising  
10 Claimant's compliance with the terms of this Decree, including all inspections,  
11 examinations, reviews, evaluations, and analyses conducted pursuant to this  
12 Decree, at the standard rates prevailing at the time the activities are accomplished.  
13 As of the date this Decree is signed by the parties, the rates are \$87.57 per hour or  
14 fraction thereof per representative for supervision other than laboratory and  
15 analytical work; \$104.96 per hour or fraction thereof per representative for  
16 laboratory and analytical work; and 51 cents per mile for travel expenses for travel  
17 by automobile; government rate or the equivalent for travel by air or other means;  
18 and the published government per diem rate or the equivalent for the areas in  
19 which the inspections are performed per representative and per day for subsistence  
20 expenses, where necessary. In the event that the standard rates generally  
21 applicable to FDA's supervision of court-ordered compliance are modified, these  
22 rates shall be increased or decreased without further order of this Court.

23       27. Claimant shall abide by the decisions of FDA and its representatives,  
24 which shall be final. All decisions specified in this Decree shall be vested in  
25 FDA's discretion and, if necessary, shall be reviewed by this Court pursuant to the  
26 arbitrary and capricious standard as set forth in 5 U.S.C. § 706(2)(A). Review by a  
27 court of any FDA decision rendered pursuant to this Decree shall be based  
28

1 exclusively upon the written record before FDA at the time of the decision. No  
2 discovery shall be taken by either party.

3 28. All notifications, correspondence, and communications to FDA  
4 required by the terms of this Decree shall reference the civil action, be prominently  
5 marked "Dominguez Foods of Washington, Inc.," and be addressed to:

6 District Director  
7 Seattle District Office  
8 U.S. Food and Drug Administration  
9 Department of Health and Human Services  
22201 23rd Drive SE  
Bothell, WA 98021-4421

10 29. Should the United States bring, and prevail in, a contempt action to  
11 enforce the terms of this Decree, Claimant shall, in addition to other remedies,  
12 reimburse the United States for its attorneys' fees and overhead, investigational  
13 and analytical expenses, expert witness fees, travel expenses incurred by attorneys  
14 and witnesses, administrative court costs, and any other costs or fees relating to  
15 such proceedings.

16 30. If Claimant has maintained a state of continuous compliance with this  
17 Decree, the Act, and its implementing regulations for at least sixty (60) months  
18 after entry of this Decree, Claimant may petition FDA for leave to ask this Court to  
19 dissolve this Decree. If, at the time of the petition, in FDA's judgment, Claimant  
20 has maintained such a state of continuous compliance, FDA will not oppose such a  
21 petition, and Claimant may request that this Decree be dissolved.

22 31. This Court retains jurisdiction over this action for the purpose of  
23 enforcing or modifying this Decree and for the purpose of granting such additional  
24 relief as may be necessary or appropriate.

25 SO ORDERED.

26 Dated this 8th day of February, 2012.

27 s/ Edward F. Shea  
28 United States District Judge



1 We hereby consent to entry of the foregoing Consent Decree:

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3  
4   
5 DOMINGUEZ FOODS OF  
WASHINGTON, INC.  
Claimant

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27  
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CONSENT DECREE